

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Hiroyuki SAITO et al.
Title: PREVENTION AND TREATMENT
OF BLOOD COAGULATION-
RELATED DISEASES
Appl. No.: 10/089,501
Filing Date: April 22, 2002
Examiner: Unassigned
Art Unit: Unassigned

INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §1.56

Commissioner for Patents
Washington, D.C. 20231

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56. A copy of each listed document is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing date of the first Office Action on the merits.

RELEVANCE OF EACH DOCUMENT

The relevance of the documents is described in the present specification.

Applicants respectfully request that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Respectfully submitted,

Date: August 23, 2002

FOLEY & LARDNER
Customer Number: 22428



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PATENT TRADEMARK OFFICE

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Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT Date Submitted: August 26, 2002 (use as many sheets as necessary)				Complete if Known	
				Application Number	10/089,501
				Filing Date	04/22/2002
				First Named Inventor	Hiroyuki SAITO, et al.
				Group Art Unit	Unassigned
				Examiner Name	Unassigned
				Attorney Docket Number	053466-0325
Sheet	1	of	3		

U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
	A1	5,346,991		ROY, et al.	09/13/1994	

FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Office ³	Number ⁴	Kind Code ⁵ (if known)				
	A2	EP	0 278 776	A2	GENENTECH, INC.	08/17/1988		
	A3	WO	88/09817	A1	MOUNT SINAI SCHOOL OF MEDICINE OF THE CITY UNIVERSITY OF NEW YORK	12/15/1988		
	A4	WO	88/07543	A1	SCRIPPS CLINIC AND RESEARCH FOUNDATION	10/06/1988		

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
	A5	DAVIE, et al., "Waterfall Sequence for Intrinsic Blood Clotting," <i>Science</i> , Vol. 145, pp. 1310-1312 (1964), USA	
	A6	GIESEN, et al., "Blood-borne tissue factor: Another view of thrombosis," <i>Proc. Natl. Acad. Sci.</i> , Vol. 96, pp. 2311-2315 (1999), Medical Sciences, USA	
	A7	TAYLOR, et al., "Lethal <i>E. coli</i> Septic Shock Is Prevented by Blocking Tissue Factor With Monoclonal Antibody," <i>Circulatory Shock</i> , Vol. 33, pp. 127-134 (1991), Wiley-Liss, Inc., USA	
	A8	MACFARLANE, "Haemotology, An Enzyme Cascade in the Blood Clotting Mechanism, and its Function as a Biochemical Amplifier", <i>Nature</i> , Vol. 202, pp. 498-499 (1964), USA	
	A9	PAWASHE, et al., "A Monoclonal Antibody Against Rabbit Tissue Factor Inhibits Thrombus Formation in Stenotic Injured Rabbit Carotid Arteries," <i>Circulation Research</i> , Vol. 74, No. 1, pp. 56-63 (1994), USA	
	A10	LEVI, et al., "Inhibition of Endotoxin-induced Activation of Coagulation and Fibrinolysis by Pentoxifylline or by a Monoclonal Anti-tissue factor Antibody in Chimpanzees," <i>The Journal of Clinical Investigation, Inc.</i> , Volume 93, pp. 114-120 (1994), USA	

Examiner Signature	Date Considered
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		Attorney Docket Number	053466-0325
Sheet	2	of	3

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
	A11	HUANG, et al., "Tumor Infarction in Mice by Antibody-Directed Targeting of Tissue Factor to Tumor Vasculature," <i>Science</i> , Vol. 275, pp. 547, 550 (1997)	
	A12	HOLST, et al., "Local Application of Recombinant Active-site Inhibited Human Clotting Factor VIIa Reduces Thrombus Weight and Improves Patency in a Rabbit Venous Thrombosis Model," <i>Eur J Vasc Endovasc Surg</i> , Vol. 15, pp. 515-520 (1998), W.B. Saunders Company Ltd., USA	
	A13	BELLAMY, et al., "Development of an orthotopic SCID mouse-human tumor xenograft model displaying the multidrug-resistant phenotype," <i>Cancer Chemother Pharmacol</i> , Vol. 37, pp. 305-316 (1996), Springer-Verlag, Germany	
	A14	RANDOLPH, et al., "Role of Tissue Factor in Adhesion of Mononuclear Phagocytes to and Trafficking Through Endothelium In Vitro," <i>Blood</i> , Vol. 92, No. 11, pp. 4167-4177 (1998), The American Society of Hematology, USA	
	A15	HIMBER, et al., "Dissociation of Antithrombotic Effect and Bleeding Time Prolongation in Rabbits by Inhibiting Tissue Factor Function," <i>Thromb Haemost</i> , Vol. 78, pp. 1142-9 (1997), Schattauer Verlag, Germany	
	A16	RAGNI, et al., "Monoclonal Antibody Against Tissue Factor Shortens Tissue Plasminogen Activator Lysis Time and Prevents Reocclusion in a Rabbit Model of Carotid Artery Thrombosis," <i>Circulation</i> , Vol. 93, No. 10, pp. 1913-1918 (1996), American Heart Association, Inc., USA	
	A17	MORRISSEY, et al., "Molecular Cloning of the cDNA for Tissue Factor, the Cellular Receptor for the Initiation of the Coagulation Protease Cascade," <i>Cell</i> , Vol. 50, pp. 129-135 (1987), Cell Press, USA	
	A18	RAN, et al., "Infarction of Solid Hodgkin's Tumors in Mice by Antibody-directed Targeting of Tissue Factor to Tumor Vasculature," <i>Cancer Research</i> , Vol. 58, pp. 4646-4653 (1998), USA	
	A19	DRAKE, et al., "Functional Tissue Factor Is Entirely Cell Surface Expressed on Lipopolysaccharide-stimulated Human Blood Monocytes and a Constitutively Tissue Factor-producing Neoplastic Cell Line," <i>The Journal of Cell Biology</i> , Volume 109, pp. 389-395 (1989), The Rockefeller University Press, USA	
	A20	CALLANDER, et al., "Immunohistochemical Identification of Tissue Factor in Solid Tumors," <i>Cancer</i> , Vol. 70, pp. 1194-1201 (1992), USA	
	A21	KONIGSBERG, et al., "The TF: VIIa Complex: Clinical Significance, Structure-function Relationships and Its Role in Signaling and Metastasis," <i>Thromb Haemost</i> , Vol. 86, pp. 757-771 (2001), Schattauer GmbH, Germany	
	A22	HARKER, et al., "Antithrombotic and AntileSION Benefits without Hemorrhagic Risks by Inhibiting Tissue Factor Pathway," <i>Haemostasis</i> , Vol. 26, pp. 76-82 (1996), S. Karger AG, Switzerland	
	A23	HOUGIE, "Reactions of Stuart Factor and Factor VII with Brain and Factor V," <i>P.S.E.B.M.</i> , Vol. 101, pp. 132-135 (1959), National Heart Institute, USA	
	A24	NAKAYAMA, et al., "Anticoagulation Therapy by Inhibiting Extrinsic Pathway," <i>TRANSLATION OF Hematology & Oncology</i> , Vol. 39, No. 4, pp. 298-302 (1999), First Department of Internal Medicine, Nagoya University School of Medicine, Japan	

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